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REMARKS

After entry of this Amendment B, claims 1-71 will be pending. Claims 1, 17, 35, 53, 56, 58, and 65 have been amended to require the composition to be suitable for ingestion by a suckling infant. Further claims 20, 40 and 71 have been amended herein to correct typographical errors. No new matter has been added by these amendments. Support for the amendments to claims 1, 17, 35, 53, 58, and 65 can be found in original claim 65, and further, throughout the instant specification.¹ Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of Claims 1-71 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-71 under 35 U.S.C. §103(a) as being unpatentable over Buckley et al. (U.S. 5,281,186) and further in view of Allen (U.S. 6,361,806).

Claim 1 is directed to a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman. The breast pad has a front side which faces the breast and a back side which faces the clothing. The front side comprises from about 0.1 g/m² to about 30 g/m² of a composition for improving breast and nipple skin health. The composition comprises omega-3 fatty acids. The composition is suitable for ingestion by a suckling infant.

Buckley et al. is directed to a protective breast cup arrangement comprising a plurality of breast cup members arranged to provide protection to an individual's breast region during

¹See, e.g., Instant specification on page 2, lines 25-32, page 4, lines 30-33, page 13, lines 25-28, page 14, lines 25-30, page 15, lines 29-32, and page 16, lines 19-21, 25-30.

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sporting events. The cup arrangement may include a nipple pad formed from a lotion impregnated fluid absorbent sponge material. The lotion is of any type commercially available to afford protection and healing to an individual's skin or nipple. Contrary to the assertion by the Office, Buckley et al. fail to disclose a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by a woman.

Significantly, Buckley et al. fail to disclose a breast pad comprising from about 0.1 g/m² to about 30 g/m² of a composition for improving breast and nipple skin health comprising omega-3 fatty acids. This is a requirement of claim 1 and is an important aspect of applicants' invention. Recognizing that Buckley et al. fail to make such a disclosure, the Office cites Allen for combination with Buckley et al. in an attempt to find each and every element of applicants' claim 1.

Allen discloses topical emollient compositions and methods that allow for topical administration of a balanced mixture of C₁₈ unsaturated fatty acids that is effective to penetrate epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues. The compositions consist of hydrophilic:hydrophobic emulsions comprising a carrier, a vehicle, a compatible balanced fatty acid penetrant consisting of C_{16:0}, C_{18:0} and C_{18:1} fatty acid derivatives, a mixture of medicinal fatty acids, a natural anti-inflammatory compound, a natural analgesic compound, a natural estrogenic compound, and a fragrance. In one embodiment, the composition may comprise an alpha linoleic omega-3 fatty acid. The composition is suitably applied to breast adipose tissues to improve cosmetic appearance such as an increase in size or shape,

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and a decrease in sagging.

In combining these references, the Office states that it would have been obvious to one of ordinary skill in the art to modify the breast pad of Buckley et al. to provide the composition taught by Allen because the composition of Allen promotes improvement of the skin. Applicants assert that such a combination is not proper, and that a careful reading of the Allen reference actually teaches away from use of their composition on a breast pad as discussed below.

As stated in M.P.E.P. §2143, in order for the Office to show a prima facie case of obviousness, the Office must meet three criteria: (1) the prior art reference(s) must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and (3) there must be some reasonable expectation of success. Applicants assert that the Office has not, and cannot, meet the burdens of either number (1) or number (2) above, which requires the Office to show each and every claim limitation and some motivation to combine the cited references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Applicants assert that the references, if combined do not contain all of the limitations of instant claim 1, nor is there motivation or suggestion to combine the references. Additionally, the Allen reference would actually have taught one skilled in the art away from its combination with Buckley et al.

As discussed in applicants' specification, the omega-3 fatty

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acid-containing composition is introduced onto the breast pad such that it contacts the surface of the breast and nipple skin during use so that it can help repair skin damage on the skin surface (stratum corneum) induced by suckling by providing lipids lost from the skin surface. In direct contrast, the composition of Allen is specifically designed to penetrate epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues; that is, the Allen composition is designed to penetrate through the stratum corneum (the lipid-containing layer of skin), through the epidermis, through the dermis, and into the underlying adipose tissue where it can stimulate changes in fatty acid metabolism. Instead of working on the surface of the skin like the composition of claim 1, the Allen composition is specifically designed to penetrate many layers of skin deep into the adipose tissue. To this end, the Allen composition comprises a penetrant, or penetration enhancing agent effective to increase the penetration of the emulsion into the subcutaneous tissues. This is in direct contrast to an application of a composition for skin repair on the surface of the skin as the composition set forth in claim 1 seeks to do.

Because the compositions of Allen comprise a penetrant and are designed to penetrate numerous layers of skin (and therefore are not designed or intended to treat the outer layer of the skin, i.e., the stratum corneum), the compositions of Allen are not suitable for use on a breast pad to improve skin and nipple health during breast feeding. The Allen compositions simply penetrate through the outer layers and deep into the skin and thus would not be of value on the stratum corneum. One skilled in the art and reading Allen would not, and could not, have been motivated to utilize the composition on a breast pad for treating

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the skin by replacing lipids on the outer layer of the skin as the Allen composition is designed to penetrate deeply into the subcutaneous layers. As such, motivation to combine these references would have been lacking.

In the alternative, even if the Allen composition can be used to treat the outer surface of the breast and nipple skin, one skilled in the art and considering the Allen reference would also have realized that the compositions of Allen are not suitable for use on a breast pad because of serious health concerns to both the mother, and the nursing infant. As such, not only is motivation to combine the references missing, the improper combination also fails to disclose each and every element of claim 1.

As mentioned in applicants' specification, the omega-3 fatty acid comprising composition introduced onto the breast pad will, to some extent, be ingested by the suckling infant as the composition is transferred from the breast pad to the breast and nipple skin to facilitate repair of skin. The composition of Allen is strictly for topical application, as mentioned throughout their disclosure, and is not designed for ingestion. There is no mention that the composition of Allen is suitable for ingestion by an infant. For example, as set forth in Example 1, Table A, the Allen composition may comprise sodium borate which, if ingested by an infant, can result in vomiting, diarrhea, shock and even death. Clearly, such a composition was not designed for use on a breast pad where the composition could ultimately be ingested by a nursing infant.

Additionally, the compositions of Allen comprise a natural estrogen compound. The introduction of an estrogen or estrogen producing compound into the tissue of a lactating mother can be

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dangerous the health of mother, and to the suckling infant. A close reading of the Allen reference by one skilled in the art leads to the inevitable conclusion that many of the chemical components suitable for use in the Allen composition for topical application are not suitable for ingestion by a suckling infant, which will happen if the composition is introduced onto a breast pad and transferred to the breast of the mother.

Based on the foregoing, the combination of references by the Office is improper as there is no motivation or suggestion to make the combination by one skilled in the art. Additionally, such a combination fails to disclose each and every element of claim 1 as there is no composition disclosed that is suitable for ingestion by an infant. As such, claim 1 is patentable.

Claims 1-16 depend from claim 1 and are patentable for the same reasons as claim 1, as well as for the additional elements they require.

Claim 17 is similar to claim 1 with the additional requirement that the composition further comprise omega-6 fatty acids. Claim 17 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 18-34 depend from claim 17 and are patentable for the same reasons as claim 17, as well as for the additional elements they require.

Claim 35 is similar to claim 1 with the additional requirement that the composition comprise essential fatty acids. Claim 35 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 36-52 depend from claim 35 and are patentable for the same reasons as claim 35, as well as for the additional elements they require.

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Claim 53 is similar to claim 1 and requires that the composition comprise flaxseed oil. Claim 53 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 54 and 55 depend from claim 53 and are patentable for the same reasons as claim 53, as well as for the additional elements they require.

Claim 56 is similar to claim 1 wherein the composition comprises linoleic acid, alpha linoleic acid, eicosapentenoic acid, and docosahexenoic acid. Claim 56 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claim 57 depends from claim 56 and is patentable for the same reason as claim 56, as well as for the additional elements it requires.

Claim 58 is directed to a method of treating or preventing nipple tenderness and cracking comprising introducing a composition, suitable for ingestion by a suckling infant, comprising omega-3 fatty acids onto a breast pad and transferring the composition from the breast pad to the breast of the wearer. Claim 58 is similar to claim 1 and is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 59-64 depend from claim 58 and are patentable for the same reasons as claim 58, as well as for the additional elements they require.

Claim 65 is similar to claim 58 and is patentable for the same reasons as claim 58, as well as for the additional elements it requires.

Claims 66-71 depend from claim 65 and are patentable for the

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same reasons as claim 65, as well as for the additional elements they require.

In view of the above, applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Amendment B and Response After RCE to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully Submitted,



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